April 20, 1999

98P 0504 '99 MAR 22 A9:28

William K. Hubbard
Associate Commissioner for Policy Coordination
Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98P-0504, Performance Standard for *Vibrio vulnificus*.

Dear Mr. Hubbard:

The Pacific Coast Oyster Growers Association (PCOGA) previously submitted comments on December 15, 1998 regarding the Center for Science in the Public Interest's (CSPI) petition requesting regulatory action to establish a standard for *Vibrio vulnificus* in raw molluscan shellfish of undetectable levels (Docket No. 98P-0504). Since that time, FDA published a request for information and views regarding eight specific questions related to CSPI's petition. While much of the information provided in our earlier response addresses the eight questions, this letter attempts to respond specifically to them.

Before addressing the questions, I would like to reiterate that PCOGA believes strongly that FDA should defer this issue to the Interstate Shellfish Sanitation Conference for deliberation. If FDA were to take unilateral action on this petition, circumventing the ISSC process, future support and involvement in the ISSC by PCOGA and other members could be seriously eroded. The Memorandum of Understanding in which FDA recognizes ISSC as the primary national organization to provide guidance on shellfish public health issues is a crucial foundation on which the effectiveness of the Conference is built.

In 1998, Issue 98-106 was submitted to the ISSC, which includes recommendations similar to those included in the CSPI petition. Conference delegates referred the issue to committee for further deliberation. This action was supported by the FDA along with a request for the committee to consider nine questions similar to the ones included in the FDA *Federal Register* Notice.

ISSC is in the process of finalizing a contract with Research Triangle Institute (RTI) to study the potential economic impact of establishing a performance standard of "non-detectable" for *Vibrio vulnificus*. The decision to conduct this study was the result of a recommendation by Mr. Phillip Spiller, Director, FDA Office of Seafood in his opening comments at the 1998 ISSC. The results of this study are crucial to any decision the ISSC or FDA could make regarding this issue.

The ISSC is working with FDA and State Shellfish Control Authorities in nine states to investigate levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in shellstock in retail establishments. The results of these efforts will also be helpful to FDA and ISSC in their consideration of this issue.

In light of the above ongoing efforts, it would seem most prudent for the FDA to either deny the petition as was requested by PCOGA in our December comments or to delay action until the results of these studies and recommendations regarding Issue 98-106 are available to FDA.

98P-0504 C189

Pacific Coast Oyster Growers Association
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In response to the eight questions posed in the *Federal Register*:

1. Is the Ameripure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

Whether the Ameripure technology is readily employable is not relevant if the finished product is not marketable. The marketability of Ameripure's finished product is unproven in PCOGA's opinion. This product is new to the market place and claims of acceptability by the proponent who stands much to gain through the sale of patent licenses and royalties are suspect. Continued application of the Ameripure process on a volunteer basis is appropriate and will ultimately determine market acceptability. Mandating the process on an entire industry could have devastating results if the product is in fact not acceptable to consumers accustomed to fresh, live, raw oysters on the half shell.

Assuming the Ameripure product were acceptable to the market, barriers that affect its employability include:

- Different treatment effectiveness for variable sized oysters, variable shell thickness, oyster species, cluster vs. single oysters, clams, mussels and scallops. To our knowledge, the Ameripure technology has not been proven effective on anything other than very uniform single Eastern oysters. The uniformity is apparently critical to the desired end result of "non-detectable" in all of the shellfish included in a particular pasteurization batch. The industry on all coasts harvest oysters of variable sizes. On the West Coast, there are a half dozen different species of oysters raised in a variety of culture systems which yield markedly different shell characteristics. Growers are concerned the Ameripure process will not accommodate the variability of their products.
- The resulting product is no longer live. It may taste similar to fresh, live raw oysters for the first few days following treatment, however the organoleptic characteristics are most certainly going to change over time compared to oysters still live in the shell. Shelf life will be reduced through the Ameripure process on some shellstock.
- Since the product is processed and no longer live shellstock, it has colder temperature (38° F) holding requirements than live oysters. Where Ameripure's product is marketed as being the same as live raw oysters, this will be confusing to the processing, distribution and retail sectors that will now have two different temperature regimes to follow for shellstock oysters.
- The cost of the patent license, royalties and processing equipment is not precisely known but is rumored to be high. West Coast Growers have heard the license to use the process could cost as much as $250,000 with a $0.02 per oyster royalty being paid to Ameripure. The equipment to process 40,000 pounds of product per day is rumored to cost as much as $800,000. If these figures are even close to being accurate, this would be a crippling burden on shellfish processors and would likely eliminate all but a few of them.

2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of *V. vulnificus* in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of *V. vulnificus* to nondetectable levels?

All the post-harvest technologies currently under study kill the animal, with the exception of irradiation, thereby changing the inherent condition of the product. Irradiation results in non-detectable levels without killing the live animal but is not approved by FDA. Freezing with liquid carbon dioxide results, reportedly, in levels approaching non-detectable. High hydrostatic pressure shows promise, but is still in the experimental stage. Short term depuration has proven ineffective in that it appears the Vibrios are part

of the normal bacterial flora of the shellfish and not readily shed and killed by disinfection systems employed in depuration. Longer term depuration may be effective but is not economical. Holding of animals in refrigerated sea water systems is a technique that may merit further review.

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

In that none of these other technologies has been proven and used extensively to produce shellfish with non-detectable levels of *Vibrio vulnificus,* it is not possible to assess their reliability. Freezing with liquid carbon dioxide is a well-established freezing technique for other food commodities. Its limited use for oysters appears to yield a quality product with characteristics similar to a fresh raw oyster if glazed and stored properly.

Depuration in itself is a reliable technology, but its application in reducing *Vibrio vulnificus* to non-detectable levels is not. Many West Coast oysters are marketed for the value of the flavors imparted by the particular growing waters. Depuration in a sterilized system, particularly for extended periods of time could eliminate these characteristics.

All of these other technologies require expensive equipment and would not be practical to impose on an entire industry or even a significant portion of the industry. The practicality of their application also is related to what species and product forms they are required to be applied to.

4. Would a performance standard have to be as low as ``non-detectable?'' Do data exist that would permit the setting of a performance standard above ``non-detectable?'' If so, at what level? Should the fact that *V. vulnificus* is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

PCOGA questions whether a performance standard is appropriate at all for an organism (*Vibrio vulnificus*) that in not "ordinarily injurious." For people in the at-risk group who choose to eat raw or raw-like product, a performance measure standard other than zero may be effective. For healthy individuals any performance standard would be ineffective and unnecessary.

If the ISSC determines a performance standard approach is appropriate, looking to months when there have been no historic reported illnesses or deaths attributed to *V. v.* could be valuable in determining what an appropriate level should be, particularly in that it is not practical to do feeding trials to establish an infectious dose.

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

The vast majority of illnesses and deaths linked to *V. v.* have been attributed to oysters consumed raw. While, as mentioned, we question the validity of applying a performance standard to an organism that is not ordinarily injurious, it most certainly should not be applied to other types of shellfish. The suggestion that FDA may even be considering this has growers of other species very alarmed (see attached newspaper clipping from *The Olympian*, 4/20/99 "Rule may kill live shellfish sales").

6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on

costs be if a standard of ``non-detectable'' were put in place for all pathogens or for all raw molluscan shellfish?

This question is very broad and difficult to answer. The study commissioned by the ISSC to be done by RTI will attempt to quantify some of these economic impacts. FDA and ISSC should utilize the results of this survey in their deliberation of this issue.

A performance standard could likely eliminate live, raw shellfish as a consumer choice. Financial costs to processors, harvesters, distributors, retailers, foodservice operators and consumers would be substantial. Some of these will be quantifiable and others not. There would be a non-quantifiable socio-economic impact and cultural loss to consumers who have traditionally eaten raw shellfish.

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

There would be a benefit to a small group of vulnerable individuals from the at-risk population that could now choose to eat post harvest treated shellfish products with a reduced risk of illness from *Vibrio vulnificus*.

8. Another marine pathogen, *V. parahaemolyticus*, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from *V. parahaemolyticus* have occurred from oysters harvested outside of the Gulf of Mexico region. Should a performance standard apply only to *V. vulnificus* or should it apply to other *Vibrio* species that post-harvest treatment might be able to reduce to nondetectable levels?

PCOGA provided extensive comments regarding whether *Vibrio parahaemolyticus* should be included in FDA's consideration of CSPI's petition in our December 15, 1998 response. We believe that any adjustment to the existing performance standard of 10,000 MPN for *V. p.* should be considered separately from any deliberation concerning *V. v.*. The ISSC adopted an interim control plan for *V. p.* in 1998 for a three year period. The results of the effectiveness of the ICP will be evaluated at the 2001 ISSC Conference. Washington State implemented the *V. p.* ICP in the summer of 1998 and achieved significantly reduced illnesses compared to the previous summer with similar climatic conditions and ambient *V. p.* levels.

In closing, the PCOGA appreciates your consideration of our comments on this important issue. We are dismayed however, that we have to deal with it outside of the context of the ISSC. The FDA has a good record of cooperation and respecting the relationships established by the MOA. We urge you to continue that cooperative spirit and allow the Conference the opportunity to deliberate this issue.

Sincerely,

Robin Downey
Executive Director

Steve Bloomfield
President

Shellfish

From Page One

other words, both vibrios and all types of shellfish could be covered.

Bishop said his entire business is based on selling live, fresh manila clams. If they are pasteurized and killed, they will lose their market value, he said.

"It would probably destroy our market, and it could destroy our business," he said.

The pasteurization could cost $250,000 for the equipment and add 40 percent to the cost of a dozen oysters, Downey said.

An awkward position

The shellfish growers acknowledge that they are in the awkward position of resisting a food safety rule designed to protect public health.

"We're not fighting it just because it's an economic hardship — we don't want to make people ill," Downey said. "But the decision to eat a raw oyster ought to be a choice that consumers can make for themselves.

"We have a serious public health problem in one part of the country being compared to a different vibrio strain in the Pacific Northwest," she continued. "We're saying to the FDA: Please don't confuse the vibrios."

Once the public comment period ends Wednesday, the Food and Drug Administration could reject it or develop a rule that mirrors, modifies or expands what is asked for in the petition. A decision on the petition is expected within the next six months, Mitchell said.

"There's no clear sense of what side of the fence the FDA is sitting," noted Jennifer Tabaldi, manager of the state Department of Health's shellfish programs.

Marine bacteria differ in severity

The Olympian

Vibrio is a naturally occurring marine bacteria that thrives in shallow, coastal waters in temperate climate.

The bacteria can accumulate in oysters, clams, scallops and fish.

At least 11 species of vibrio are known to cause illness in humans. Two of the species, Vibrio vulnificus and Vibrio parahaemolyticus, are well-known to shellfish growers, regulators and food safety consumer groups.

■ **Vibrio vulnificus:** The more potent of the two species, it has been implicated in 89 deaths and 88 severe illnesses from acute blood poisoning since 1989, chiefly among consumers of raw oysters harvested from Gulf Coast states.

Most at risk are raw oyster consumers with liver disease, cancer, diabetes, kidney disease and those who are HIV-positive.

Primarily found in the Gulf of Mexico, this vibrio species has been isolated from Pacific and Atlantic ocean water samples.

■ **Vibrio parahaemolyticus:** This species is more widespread than vulnificus, but not as potent. Illness from infection include flu like symptoms, with a few case requiring hospitalization.

In 1997-98, confirmed illnesse associated with Washingtor grown oysters totaled 116, incluc ing 73 from commercially grow product.

All people who consume raw o improperly cooked shellfish an fish are vulnerable to infection.

Major outbreaks from eithe species are most common in th warmer months of the year.

Neither organism can be seen smelled or tasted. They are botl easily killed by cooking.

AT A GLANCE

To get involved

The U.S. Food and Drug Administration is seeking public comment by Wednesday on a petition that could eliminate the sale of live, raw oysters by commercial shellfish growers. Comments should be addressed to William K. Hubbard, Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

The FDA is expected to rule on the petition in about six months.

Possibilities

The state is making the following recommendations to the FDA:

■ **Limit any** new rule to oysters, the shellfish species most commonly eaten raw.

■ **Adopt the** non-detect standard for Vibrio vulnificus only in oyster-growing states implicated with an illness or death.

During the 1998 outbreak of Vibrio parahaemolyticus in Puget Sound, the state tested for, but did not find, Vibrio vulnificus in oyster tissue or water samples, Tabaldi said.

There have been no Vibrio vulnificus illnesses traced to Washington shellfish since it was formally recognized as a reportable illness in 1988, according to state health officials.

■ **Allow more time** for state regulators and the industry to research what constitutes an infectious dose of vibrio in shellfish.

Tabaldi and the shellfish growers said the proper forum to address vibrio and public health is the Interstate Shellfish Sanitation Conference, which consists of shellfish industry members, regulators and the FDA.

The group adopted interim r last year used by South Puget So shellfish growers to voluntarily the sale of live oysters for raw c sumption last August after an o break of Vibrio parahaemolyticu

Once the ban went into place, illnesses stopped, Downey said.

But the interstate group has ye agree on strict protocol to red the risk of a Vibrio vulnificus c break.

The FDA estimates that betw 12 million and 30 million Americ have health problems that put th at risk to a Vibrio vulnificus infect

"Something needs to be d about the Vibrio vulnificus deat Tabaldi agreed. "But give us anotl year or two to do the research."

Another year or two is too lon wait, said Mitchell, the consur group's attorney.

John Dodge covers the envir ment for The Olympian. He can reached at 754-5444.

Rule may kill live shellfish sales

FDA PETITION: Food safety advocates may be unnecessarily targeting Puget Sound, growers say.

By John Dodge
The Olympian

OLYMPIA — The state's commercial shellfish growers say a food safety petition filed with the U.S. Food and Drug Administration represents a threat to their livelihoods.

At issue is whether the shellfish industry can keep selling live shellfish for raw consumption.

The Center for Science in the Public Interest, a Washington, D.C., consumer safety group, says too many people are dying or getting seriously ill each year from eating bacteria from tainted, raw shellfish, chiefly oysters.

The group filed a petition with the FDA last June, urging the federal agency to require raw shellfish be sold with nondetectable levels of Vibrio vulnificus, a potentially lethal strain of a natural bacteria that thrives in warm water.

The deadline for public comment on the petition is Wednesday.

Since 1989, this Vibrio species has been blamed for 177 serious illnesses and deaths, most of them linked to oysters harvested from the Gulf Coast.

Food safety advocates said the FDA could require growers to kill the bacteria by pasteurizing their shellfish before selling them.

"Our goal is a safer product through some sort of post-harvest treatment," said Darwin Mitchell, a food safety staff attorney for the Center for Science in the Public Interest.

While the petition to FDA singles out Gulf Coast oysters as the target, it leaves the door open for a regulation that effects Washington's $60 million shellfish industry, too, said Robin Downey, executive director of the Olympia-based Pacific Coast Oyster Growers Association.

Here in Washington, another, less virulent, strain called Vibrio parahaemolyticus has led to dozens of illnesses among raw oyster consumers in the past two years, and 700 illnesses nationwide. But it's more like the flu than a life-threatening dose of Vibrio vulnificus.

Nevertheless, the FDA is asking the question: Should any new standard apply to both Vibrios?

"It would be a lot simpler for the FDA to have a one-size-fits all regulation," worries Brett Bishop, owner of Little Skookum Shellfish Growers in Mason County. In

See Shellfish / **A2**

Tony Overman/The Ol

HEAT IS ON: Brett Bishop, owner of Little Skookum Shellfish Growers, says an FDA rule requiring shellfish pasteurized could destroy his business. He sells his manila clams live.

SAFE EATING TIPS

Here are some tips to reduce the risk of illness from the consumption of raw oysters:

- **BUY ONLY** from certified sources. At a retail store or restaurant. ask to see the shellfish certification tag that ensures the oyster is from an approved growing area.
- **KEEP RAW** oysters refrigerated and eat them soon after purchase.
- **IF THE** oyster is dea — for instance, it has an open, gaping shell — do eat it.
- **AVOID EATING** raw shellfish if you have a co promised immune syste

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